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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/486,623 | 07/06/2000 | PETER E. NIELSEN | ISIS-3292 | 9879 |

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07/01/2002

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EXAMINER

MARSCHER, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 07/01/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,623

Applicant(s)

Nielsen et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 25-28, 31-42, and 45-56 is/are pending in the application.
- 4a) Of the above, claim(s) 31-42 and 45-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25-28, 55, and 56 is/are rejected.
- 7) ☒ Claim(s) 1-22, 24, 29, 30, 43, and 44 have been canceled. ~~are objected to~~
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' arguments, filed 4/23/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 55 and 56 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The NEW MATTER rejection of claim 55 is maintained and reiterated from the previous office action, mailed 12/31/01. Applicants argue that the disinfecting of objects that have been contaminated with a particular bacteria gives support for the claim 55 identifying. In response killing or inhibiting a particular bacteria is one step which does not require nor give written basis for an identifying step. It is acknowledged that a PNA disinfectant may be designed for killing or inhibiting a particular bacteria but this would require a specific prior determination of what bacteria is the design target which does not require identification of a bacteria. Rather selection of a bacteria from a list of bacteria via some selection criteria might be performed. Such selection is not the identification of

an unknown bacteria nor does it require an assay for bacteria identification. Also, such a selection for PNA design must occur prior to any killing or inhibition whereas the identifying step in claim 55 is not limited to being prior, during, or after the killing or inhibiting step thus also supporting this rejection.

The NEW MATTER rejection of claim 56 is maintained and reiterated from the previous office action, mailed 12/31/01. Applicants argue that the specific Example 7 agar growth assay demonstrates that applicants had possession of generic methods for examining the killing or inhibiting of bacterial growth as cited in claim 56. It is reiterated from the previous office action, mailed 12/31/01, that examination broadly includes some process for such examination such as visual inspection, immunoassays, etc. whereas only the agar cell growth assay practice is present on page 22. None of these other methods have written basis as filed nor even a pointing to other such generic methods as usable for such examination. Therefore applicants' arguments are non-persuasive. Applicants further argue that a skilled artisan would be able to employ routine laboratory experimentation to examine PNA effects on target bacteria. This is acknowledged, but such abilities still do not add written support for such routine laboratory experimentation as being contemplated by applicants at the time of filing. The issue in this rejection is written support for claim limitations and not

what skilled artisans may or may not be able to perform.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23 and 25-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 12 of U.S. Patent No. 6,300,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because common embodiments of antibiotic in-vitro bacterial killing are present in both sets of claims. This rejection is reiterated and maintained from the previous office action, mailed 12/31/01. Applicants firstly argue that the disclosure of a patent may not be used as prior art. This argument is confusing in that the above repeated rejection lacks any pointing to the disclosure of a patent other than the cited claims. Then applicants argue that there has not

been supplied any motivation to modify the cited reference to render the present claims obvious. In response no such motivation is needed because the claims themselves support the obviousness of overlapping embodiments. For example, claim 6 of the Patent cites PNA which is antiparallel to messenger RNA just as instant claim 25 does. Claim 3 of the Patent cites the added usage of at least one antibiotic as does instant claim 26. Claims 1 and 4 of the Patent are directed to killing or inhibiting growth via PNA directed to ribosomal and messenger RNA as well as antisense oligomer lengths as in claims 27 and 28 which are extremely well known targets for antisense inhibition or killing as performed by a PNA reagent. Thus, the basis for these aspects of the rejection relies on what is extremely well known in the art. Since no modification of the claims are needed to support this rejection, then there is no need to teach a reasonable expectation of success as they are the same embodiments with the same expectation of success as would be expected for the same embodiments.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 31-42 and 45-54, drawn to an invention non-elected without traverse in Paper No. 8, filed 10/18/01. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 28, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER